4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 133

[Docket No. FDA-2008-P-0086]

Cheeses and Related Cheese Products; Proposal to Permit the Use of Ultrafiltered Milk; Reopening the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is reopening the comment period for the proposed rule published in the *Federal Register* of October 19, 2005, entitled "Cheeses and Related Cheese Products; Proposal to Permit the Use of Ultrafiltered Milk." The proposed rule would amend our regulations to provide for the use of fluid ultrafiltered (UF) milk in the manufacture of standardized cheeses and related cheese products. We are reopening the comment period to receive new information and further comment on current industry practices regarding the use of fluid UF milk and fluid UF nonfat milk in the manufacture of standardized cheeses and related cheese products, and the declaration of fluid UF milk and fluid UF nonfat milk when used as ingredients in standardized cheeses and related cheese products.

DATES: FDA is reopening the comment period on the proposed rule published on October 19, 2005 (70 FR 60751). Submit either electronic or written comments by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before

[INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2008-P-0086 for "Cheeses and Related Cheese Products; Proposal to Permit the Use of Ultrafiltered Milk." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as

"confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Daniel Reese, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2371.

SUPPLEMENTARY INFORMATION:

I. Background

In the *Federal Register* of October 19, 2005, we proposed to amend our regulations to provide for the use of fluid UF milk in the manufacture of standardized cheeses and related cheese products. Specifically, the proposed rule, if finalized, for standardized cheeses and related cheese products, would (1) amend the definitions of "milk" and "nonfat milk" in § 133.3 (21 CFR 133.3) to provide for ultrafiltration of milk and nonfat milk; and (2) define ultrafiltered milk and ultrafiltered nonfat milk in § 133.3 as raw or pasteurized milk or nonfat milk that is passed over one or more semipermeable membranes to partially remove water, lactose, minerals, and water-soluble vitamins without altering the casein-to-whey protein ratio of the milk or nonfat

milk and resulting in a liquid product. FDA also proposed that the name of such treated milk be "ultrafiltered milk" or "ultrafiltered nonfat milk," as appropriate. Consequently, when this type of milk is used, it would be declared in the ingredient statement of the finished food as "ultrafiltered milk" or "ultrafiltered nonfat milk."

This proposal was issued in response to citizen petitions from the American Dairy Products Institute and the National Cheese Institute, the Grocery Manufacturers of America, Inc., and the National Food Processors Association. Interested persons were originally given until January 17, 2006, to comment. We subsequently reopened the comment period to seek further comment on two specific issues raised by the comments concerning the proposed ingredient declaration (72 FR 70251, December 11, 2007); the reopened comment period was scheduled to end on February 11, 2008. In the *Federal Register* of February 11, 2008 (73 FR 7692), we extended the comment period until April 11, 2008.

In the *Federal Register* of August 14, 2017 (82 FR 37815), we announced the availability of a guidance for industry entitled "Ultrafiltered Milk in the Production of Standardized Cheeses and Related Cheese Products." In the guidance, we notified manufacturers who wish to use UF milk or UF nonfat milk in the production of standardized cheeses and related cheese products of our intent to exercise enforcement discretion regarding the use of fluid UF milk and fluid UF nonfat milk in the production of standardized cheeses and related cheese products, provided that the physical, chemical, and organoleptic properties of the cheese or cheese product are not affected. We also stated our intent to exercise enforcement discretion with respect to the labeling of fluid UF milk and fluid UF nonfat milk in recognition of the costs and logistics involved in label changes; however, we encouraged industry to identify these ingredients as "ultrafiltered milk" and "ultrafiltered nonfat milk" to the extent feasible and appropriate. We further explained

that we intend to exercise enforcement discretion until we have completed a rulemaking process amending our regulations with respect to the issues covered by the guidance or announced our determination not to proceed with such a rulemaking.

II. Additional Issues for Consideration

To inform our decision on whether to proceed with the rulemaking initiated in the October 19, 2005, proposal, we seek new information and public comment on current industry practices regarding the use of fluid UF milk and fluid UF nonfat milk in the manufacture of standardized cheeses and related cheese products, and the declaration of fluid UF milk and fluid UF nonfat milk in the labeling of these products when used as ingredients. Of particular interest, we seek comment on the following questions:

1. We would like to understand whether there is variable use of fluid UF milk or fluid UF nonfat milk in the production of standardized cheeses and related cheese products. For example, if a company uses fluid UF milk in the production of a standardized cheese, does the amount of fluid UF milk remain constant, or does the amount vary depending on certain factors (such as the cost of fluid UF milk)? Please explain whether the amount of fluid UF milk or fluid UF nonfat milk varies for specific standardized cheeses and related cheese products and the factors that influence the variability. To maintain the essential characteristics of the standardized cheese or cheese product, is the amount of fluid UF milk or fluid UF nonfat milk limited to a range (i.e., a minimum and maximum amount)? Please identify the specific standardized cheese or cheese product and provide any ranges or amounts and explain your reasoning.

2. (a) We invite comment on why manufacturers may sometimes produce their particular brands of standardized cheeses and related cheese products with fluid UF milk or fluid

UF nonfat milk and sometimes without fluid UF milk or fluid UF nonfat milk. Please explain your reasoning.

(b) Given that manufacturers may sometimes choose to produce these products with or without fluid UF milk or fluid UF nonfat milk, we are interested in how ingredient labeling of these standardized cheeses and related cheese products could be addressed.

Our understanding is that fluid UF milk and fluid UF nonfat milk, when used as ingredients in cheese, are always used in lesser amounts by weight than milk and nonfat milk in order to avoid affecting the physical, chemical, and organoleptic properties of the cheese. For example, a manufacturer might use milk and fluid UF milk, but our understanding is that the amount of fluid UF milk will be less than that of milk. As such, milk would be the predominant ingredient and declared first in the ingredient statement, per FDA's regulations that require ingredients to be declared by their common or usual names in descending order of predominance by weight (21 CFR 101.4(a)). Fluid UF milk, if used, would be declared thereafter.

Based on our understanding, we are considering whether, when fluid UF milk and fluid UF nonfat milk are sometimes used as ingredients, the labeling of standardized cheeses and cheese products may alternatively declare "milk or milk and ultrafiltered milk" or "nonfat milk or nonfat milk and ultrafiltered nonfat milk" in the ingredient statements. We invite comment on this consideration and whether such declarations would indicate that fluid UF milk or fluid UF nonfat milk may be an ingredient, but not as predominant as milk or nonfat milk, and also enable manufacturers to avoid relabeling costs if they use varying amounts of fluid UF milk or fluid UF nonfat milk. Please discuss whether such declarations would be informative (or, conversely, potentially misleading to consumers) and please explain your reasoning.

3. We also are interested in issues related to the costs of printing different product labels and the logistics involved in label changes when fluid UF milk and fluid UF nonfat milk are sometimes used as ingredients in the production of a manufacturer's standardized cheese or cheese product. For example, what impacts, if any, would a label statement of "milk or milk and ultrafiltered milk" or "nonfat milk or nonfat milk and ultrafiltered nonfat milk" have on labeling costs? How would these costs compare if fluid UF milk and fluid UF nonfat milk are declared only when used in the standardized cheese or cheese product? Please explain your reasoning.

4. Ultrafiltered milk is being used in a greater number of food products than in the past. There are dairy products in the marketplace, which appear to have gained consumer acceptance, where "ultrafiltered milk" has appeared in the statement of identity or declared in the ingredient statement on the product label. Are there any situations where retailers or consumers would not purchase standardized cheeses or cheese products labeled as containing "ultrafiltered milk" as an ingredient? Please describe such situations and provide any recent consumer data or market analyses you may have to explain your reasoning.

Dated: December 19, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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